

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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FERRING B.V., FERRING
INTERNATIONAL CENTER S.A., and
FERRING PHARMACEUTICALS INC.,

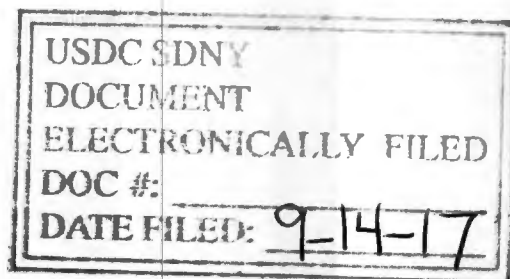
12 Civ. 2650

SEALED OPINION

Plaintiffs and Counter-
Defendants,

-against-

ALLERGAN, INC., ALLERGAN USA, INC.,
ALLERGAN SALES, LLC, SERENITY
PHARMACEUTICALS CORPORATION,
SERENITY PHARMACEUTICALS, LLC,
REPRISE BIOPHARMACEUTICS, LLC,
SEYMOUR H. FEIN, and RONALD V. NARDI,



Defendants and
Counterclaimants.

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Sweet, D.J.

Defendants Serenity Pharmaceuticals Corporation and Serenity Pharmaceuticals, LLC ("Serenity") and Reprise Biopharmaceuticals, LLC ("Reprise") (collectively, the "Counterclaim Plaintiffs") have moved pursuant to Federal Rule of Civil Procedure 25(c) for substitution of Counterclaim Plaintiffs in place of Defendants Allergan, Inc., Allergan USA, Inc., and Allergan Sales, LLC ("Allergan") in this patent infringement action.¹ Ferring B.V., Ferring International Center S.A., and Ferring Pharmaceuticals Inc. ("Ferring" or the "Plaintiffs") have moved pursuant to Federal Rule of Civil Procedure 12(b) to dismiss the counterclaims of Allergan for which the Counterclaim Plaintiffs seek substitution for lack of standing. Based on the facts and conclusions set forth below, the motion of the Counterclaim Plaintiffs is granted, and the motion of Ferring is denied without prejudice to renew.

This action has presented an ever-changing kaleidoscope of patent law issues since its inception by Ferring on April 5, 2012. It is hoped that all these issues will be determined at the trial presently scheduled for October 10, 2017.

¹ Allergan has joined in Counterclaim Plaintiffs' motion for substitution. (See Dkt. No. 277.)

Prior Proceedings

This patent infringement action was filed by Ferring on April 5, 2012. Allergan's motion to dismiss the complaint and Ferring's motion for summary judgment on Allergan's counterclaims have been resolved by opinions of March 19, 2013, and January 7, 2016, respectively. See Ferring B.V. v. Allergan, Inc., 932 F. Supp. 2d 493 (S.D.N.Y. 2013) (motion to dismiss); Ferring B.V. v. Allergan, Inc., 166 F. Supp. 3d 415 (S.D.N.Y. 2016) (motion for summary judgment). Discovery was completed in 2015. What has remained at issue are the counterclaims initially asserted by Allergan seeking a determination that Dr. Seymour Fein ("Fein") is the co-inventor of U.S. Patent Nos. 7,560,429 ("the '429 Patent") and 7,947,654 ("the '654 Patent," and, with the '429 Patent, the "Ferring Patents").

On July 10, 2017, Ferring moved to dismiss the counterclaims of Allergan and the putative counterclaims of Serenity and Reprise for lack of standing and to seal portions of their submissions. (Dkt. Nos. 263, 266.) On July 11, 2017, Counterclaim Plaintiffs moved to be substituted for Allergan as counterclaimants, (Dkt. No. 269), and on July 24, 2017, to seal

portions of their submissions, (Dkt. No. 282). The motions were heard and marked fully submitted on August 9, 2017.

Facts

The facts and prior proceedings of this litigation have been previously set forth in the opinions of the Court dated March 19, 2013, August 7, 2013, March 13, 2014, January 7, 2016, June 14, 2016, and October 28, 2016. Familiarity is assumed. The following facts provide a summary retelling as relevant to the instant motion.

i. The Ferring Patents

In 1987, Ferring introduced oral tablets containing desmopressin, which Ferring researched throughout the 1990s.² Ferring, 166 F. Supp. 3d at 417. By May 2001, Ferring had confirmed the feasibility of a quick-dissolving sublingual, or orodispersible, form of desmopressin and, by August 2001, Ferring decided to develop this formulation commercially.³ Id.

² Desmopressin is a synthetic hormone used to treat disorders related to excessive urine production. Ferring, 166 F. Supp. 3d at 417.

³ Orodispersible formulations are solid unit dosage forms, which disintegrate in the mouth within a minute in the presence

Around this time, Fein became involved with Ferring and the development of desmopressin. Id.

On May 7, 2002, Ferring filed Great Britain Patent Application No. GB0210397.6 (the "GB Application"), which disclosed a "pharmaceutical dosage form of desmopressin adapted for sublingual absorption" and named no inventor. Id. at 418. In the succeeding months and throughout the early 2000s, Fein and Ferring proceeded to file many patents regarding this subject matter. See Ferring B.V. v. Allergan, Inc., No. 12 Civ. 2650 (RWS), 2015 WL 5671799, at *2-*3 (S.D.N.Y. Sept. 22, 2015) (detailing the many Fein and Ferring patents). Two of Ferring's patents based on the GB Application are of relevance to the present inquiry, the histories for which continue below.

On September 20, 2002, Ferring filed PCT application IB02/04036, claiming the same subject matter as the GB Application and naming Fein as one of the inventors. Ferring, 166 F. Supp. 3d at 418. Fein has since asserted that he holds the patents on low dose, sublingual inventions covered by the GB Application. See Ferring, 2015 WL 5671799, at *8; (Declaration

of saliva due to super disintegrants in the formulation. Ferring, 166 F. Supp. 3d at 417 n.2 (citation and quotation marks omitted).

of Dr. Seymour Fein dated July 24, 2017 ("Fein Decl."), at 2, Dkt. No. 281).

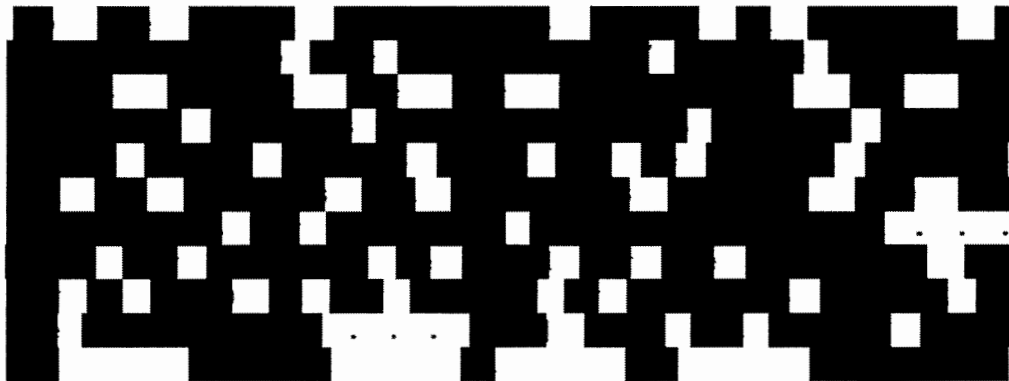
On May 7, 2003, Ferring filed a modified PCT application IB03/02368 (the "PCT Application") that claimed priority to the GB Application, removed low dose and sublingual claims from the application, and did not name Fein as an inventor. Ferring, 166 F. Supp. 3d at 418.

On June 18, 2009, as a continuation of the PCT Application, Ferring filed U.S. Application No. 10/513,437 (the "'437 Application"), which was issued on July 14, 2009, as the '429 Patent. Id. Also on June 18, 2009, Ferring filed U.S. Application No. 12/487,116 (the "'116 Application") as a continuation of the '437 Application, and to which, on November 6, 2009, a claim was added directed to "[a]n orodispersible pharmaceutical dosage form of desmopressin acetate which disintegrates in the mouth within 10 seconds." Id. Ferring did not include Fein as an inventor on this patent application either. Id. On May 24, 2011, the '116 Application issued as the '654 Patent. Id.

ii. March 2007 Agreement Assignment to Reprise

In March 2007, Fein assigned intellectual property rights in his desmopression inventions to Reprise, a corporation in which Fein was a principal and equity partner. See Ferring, 2015 WL 5671799, at *6; (Declaration of Charles T. Collins-Chase dated July 10, 2017 ("Collins-Chase Decl."), Ex. C (the "March 2007 Agreement," Dkt. No. 265; Fein Decl., at 3). Fein had also previously had formed Serenity, through which Fein and others intended to commercially market Fein's inventions. Ferring, 2015 WL 5671799, at *6.

Under the terms of the March 2007 Agreement, Fein assigned to Reprise his entire right in:



(March 2007 Agreement, at Non-AGN 00098046.)

Appendix A to the March 2007 Agreement detailed the rights in the [REDACTED] being transferred to Reprise.⁴ (Id., at Non-AGN00098046; see id., at Non-AGN00098048-50.) [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]:

[REDACTED]

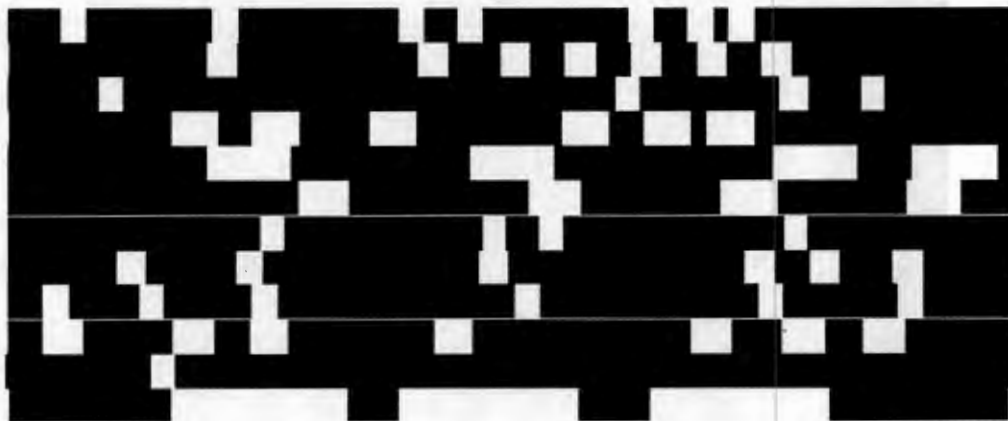
(Declaration of Christopher J. Harnett dated July 24, 2017 ("Harnett Decl."), Ex. 4, at FERALL0000075, Dkt. No. 280; see id., FERALL0000063.) The '761 Patent claimed priority over the GB Application. (See id., at FERALL0000063.) [REDACTED]

[REDACTED]

⁴

[REDACTED]
[REDACTED]
[REDACTED] The parties do not dispute that what has been presented is what was intended to be attached to the March 2007 Agreement.

Appendix A further describes the [REDACTED] assigned to Reprise through an abstract, which describes the transferred invention rights as:



(March 2007 Agreement, at Non-AGN0009850.)

iii. The Three-Way Agreement and the March 2010 Agreement with Allergan

On March 31, 2010, Allergan entered into agreements with Reprise and Serenity to assist with the development of low dose desmopressin formulations, which culminated in several agreements detailing the assignment of all rights, title, and interest in Fein's desmopressin invention patents from Reprise to Allergan and to which Serenity was also a contractual party. See Ferring, 2015 WL 5671799, at *7; (Collins-Chase Decl., Ex. B (the "Three-Way Agreement"); Declaration of Shehla Wynne dated

July 11, 2017 ("Wynne Decl."), Ex. 2 (the "March 2010 Agreement"), Dkt. No. 271).

The Three-Way Agreement states, in relevant part, that

[REDACTED]

[REDACTED]

[REDACTED] (Three-Way Agreement, at

AGN_FER000004989.) The Three-Way Agreement defines [REDACTED]

[REDACTED] as:

[REDACTED]

(Id., at AGN_FER000004985.)

The Three-Way Agreement defines [REDACTED] as the [REDACTED]

[REDACTED] (Id., at AGN_FER000004986.)

The Three-Way Agreement's [REDACTED] [REDACTED]
[REDACTED] (Id., at
AGN_FER000005010).⁵ The March 2010 Agreement does not list any
[REDACTED]
[REDACTED], the sections detailing assigned Reprise and Serenity
patent rights to Allergan. (See March 2010 Agreement, at
AGN_FER0000051390-40.)

Lastly, the Three-Way Agreement [REDACTED]
[REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED] which included [REDACTED]
[REDACTED] low dose desmopressin. (Three-Way
Agreement, at AGN_FER000004988-89.)

⁵ The Reprise patent assignments noted in Exhibit 1.2 of the Three-Way Agreement were identical to the assignments listed in the relevant sections of the March 2010 Agreement. (See Collins-Chase Decl., Ex. E, at 103:22-105:11, 111:21-112:13.)

iv. Dissolution of the Three-Way Agreement

On March 6, 2017, the Food and Drug Administration's ("FDA") approved a new product developed by Allergan and Serenity, at which point Allergan chose to exercise its contractual option to withdraw from the Three-Way Agreement and the March 2010 Agreement. (See Wynne Decl., Ex. 1, at 3; Declaration of Shehla Wynne dated August 1, 2017 ("Wynne Decl. 2"), Ex. 3, Dkt. No. 291.) Under those terms, all of the rights, title, and interest acquired by Allergan under the Three-Way Agreement reverted to Reprise and Serenity effective May 28, 2017. (See March 2010 Agreement § 13.5(b); Three-Way Agreement, at AGN_FER000005003.)

The Applicable Standards

A court may dismiss a case "for lack of subject matter jurisdiction under Rule 12(b)(1) when [it] lacks the statutory or constitutional power to adjudicate it." Makarova v. United States, 201 F.3d 110, 113 (2d Cir. 2000) (citing Fed. R. Civ. P. 12(b)(1)). When there are disputed factual issues, a district court may "resolve them in the manner it sees fit" and may refer to evidence outside the pleadings. Advanced Video Techs., LLC v.

HTC Corp., 103 F. Supp. 3d 409, 415 (S.D.N.Y. 2015) (citing Alliance For Env'tl. Renewal, Inc. v. Pyramid Crossgates Co., 436 F.3d 82, 87-88 (2d Cir. 2006)), aff'd, 677 F. App'x 684 (Fed. Cir. 2017). Furthermore, "in any case requiring determination of Article III standing, once [a] motion to dismiss for lack of jurisdiction under Fed. R. Civ. P. 12(b)(1) put[s] . . . Article III standing in issue, [a] District Court has leeway as to the procedure it wishes to follow." Alliance For Env'tl. Renewal, Inc. v. Pyramid Crossgates Co., 436 F.3d 82, 87-88 (2d Cir. 2006). A plaintiff asserting subject matter jurisdiction has the burden of establishing its existence by a preponderance of the evidence. Makarova, 201 F.3d at 113.

When stating a claim for correction of inventorship under 35 U.S.C. § 256, a party must satisfy "the requirements for constitutional standing—namely injury, causation, and redressability." Larson v. Correct Craft, Inc., 569 F.3d 1319, 1326 (Fed. Cir. 2009). A party can demonstrate constitutional standing by showing an ownership or concrete financial interest in the patent, see id. at 1326-27, or "concrete and particularized reputational injury," Shukh v. Seagate Tech., LLC, 803 F.3d 659, 663 (Fed. Cir. 2015). In the context of patent ownership assignments, federal law requires that such

conveyance be in writing. See Advanced Video Techs., 103 F. Supp. 3d at 417 (citing 35 U.S.C. § 261); see also Abraxis Bioscience, Inc. v. Navinta LLC, 625 F.3d 1359, 1366 (Fed. Cir. 2010) ("[A]n appropriate written assignment is necessary to transfer legal title from one to the other."). Standing must be shown as of the date the suit was filed. Advanced Video Techs., 103 F. Supp. 3d at 416 ("[A] plaintiff who lacks 'enforceable title to [a] patent at the inception of [his] lawsuit' will be unable to show 'injury in fact,' and is thus unable to meet his burden to show that he has Article III standing to pursue his claim." (quoting Abraxis Bioscience, 625 F.3d at 1363)).

Federal Rule of Civil Procedure 25(c) provides that "[i]f an interest is transferred, the action may be continued by or against the original party unless the court, on motion, orders the transferee to be substituted in the action or joined with the original party." Fed. R. Civ. P. 25(c). Rule 25(c) "substitution is a procedural mechanism designed to facilitate the continuation of an action when an interest in a lawsuit is transferred and does not affect the substantive rights of the parties." Fashion G5 LLC v. Anstalt, No. 14 Civ. 5719 (GHW), 2016 WL 7009043, at *2 (S.D.N.Y. Nov. 29, 2016) (quoting Travelers Ins. Co. v. Broadway W. St. Assocs., 164 F.R.D. 154,

164 (S.D.N.Y. 1995)). Decisions made pursuant to Rule 25 are "generally within the sound discretion of the trial court." In re Rates - Viper Patent Litig., No. 09 Civ. 4068 (LTS), 2011 WL 856261, at *1 (S.D.N.Y. Mar. 10, 2011) (quoting Organic Cow, LLC v. Ctr. for New Eng. Dairy Compact Research, 335 F.3d 66, 71 (2d Cir. 2003)) (internal quotation marks omitted). As such, "[t]he primary consideration in deciding a motion pursuant to Rule 25(c) is whether substitution will expedite and simplify the action." Id.

The Motion to Substitute is Granted and The Motion to Dismiss is Denied

i. The Standing Issues Require a Factual Determination and are Appropriately Determined at Trial

The issue presented by the instant motions is whether Fein assigned to Reprise and, in turn, Allergan, any intellectual property rights which Defendants contest that Fein helped invent and which have been incorporated into the Ferring Patents. Counterclaimants contends the assignments occurred in two steps: Fein assigned particular patent applications and the [REDACTED] embodied in those applications to Reprise in the March 2007 Agreement, it was the parties' intent to assign all of Fein's rights, title, and interest in low dose desmopressin

inventions—his alleged inventive contributions to the Ferring Patents—and those rights were then assigned to Allergan under the terms of the Three-Way Agreement.⁶ Ferring contends that the terms of both agreements, and principally the failure to identify any Ferring patents or applications in any of the assignment documents, removes the Counterclaimants' ability to claim standing.

After a review of the assignment agreements, each can establish that Fein's intellectual property rights have been transferred. Yet the scope of the transferrable rights—namely, if Fein had any relevant rights to transfer in the first place—remains tethered to the degree to which Fein can ultimately establish that he was involved in the invention of the Ferring Patents. As such, the question of standing is best resolved at trial while substitution of the parties is appropriate at this time.

⁶ The Counterclaim Plaintiffs' argument of untimeliness as to the question of standing is incorrect. Although at times frustrating, standing "represents a jurisdictional requirement which remains open to review at all stages of the litigation." Nat'l Org. for Women, Inc. v. Scheidler, 510 U.S. 249, 255 (1994)

The March 2007 Agreement can be read to transfer any interests Fein had in low dose desmopressin to Reprise. As detailed above, [REDACTED], that claimed intellectual property rights to inventions that underlay the GB Application, the same intellectual property contested by the parties today and which also led to the Ferring Patents. Furthermore, the [REDACTED] at the time of the March 2007 Agreement is reasonable: neither patent had been issued, nor at the time did Fein believe that Ferring was stating a claim to his claimed inventions. See Ferring, 2015 WL 5671799, at *8 (S.D.N.Y. Sept. 22, 2015); (Harnett Decl., Exs. 2-3; Fein Decl., at 2-3). As such, the March 2007 Agreement is "reasonably susceptible to [Counterclaimants'] proffered interpretation" and permits the conclusion that Reprise received through the March 2007 Agreement the contested property rights. Intellectual Ventures I LLC v. Erie Indem. Co., 850 F.3d 1315, 1322 (Fed. Cir. 2017).

Similar considerations undergird the conclusion that the Three-Way Agreement and March 2010 Agreement could have transferred Reprise's rights in Fein's intellectual property to Allergan. Like the March 2007 Agreement, neither the Three-Way

Agreement nor March 2010 Agreement [REDACTED]

[REDACTED]; however, as described above, the agreements assign to Allergan [REDACTED]

[REDACTED]

Like the March 2007 Agreement, these inclusions indicate an intention to assign to Allergan whatever rights Fein possessed at the time in the invention of low dose desmopressin and previously given to Reprise. Evidence presented indicates that this was the intension of the parties at the time. (See Fein Decl., at 3.) [REDACTED]

in the agreement does not impact this interpretation, particularly since at that time, the degree to which Fein had any claim to inventorship of those patents was unresolved.

Ferring has noted that because the Three-Way Agreement [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (Three-Way Agreement, at AGN_FER000004986.) In

addition, the agreement stated [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] (Three-Way Agreement, at
AGN_FER000004999.) To the extent that Ferring was a co-inventor
of the Ferring Patents, Ferring argues that such clauses
demonstrate that the Ferring Patents cannot fall within the
scope of the assignments.

While the [REDACTED] language as described above appears
to assign Dr. Fein's rights, if any, to Allergan under the
different 2010 agreements, that interpretation is in tension and
could be inconsistent with the provisions relied upon by
Ferring. However, whether the conflicting provisions resulted
from a scrivener's error or an incorrect representation,
particularly in light of the intent of the parties, presents
factual disputes irresolvable on the instant motion and should
be addressed at trial.

Moreover, whether the rights could have been transferred
under the terms of the agreements described above is only part
of the question; what is similarly irresolvable at present, and
remains to be determined, is the nature and breadth of the

rights transferred by Fein. That question forms the very basis of the pending trial, where the question of Fein's inventorship of the Ferring Patents is to be determined. The extent to which Fein had rights in Ferring Patents, and the relationship between Ferring and Fein in the inventorship of the intellectual property implicated in the Ferring Patents, directly connects with the degree to which Fein was an owner of such intellectual property, sole or otherwise. As such, "[w]here an issue of standing is so closely related to, if not inextricably entwined with, an issue on the merits, district courts have some leeway as to the procedure it wishes to follow." Leighton Techs. LLC v. Oberthur Card Sys., S.A., 531 F. Supp. 2d 591, 594 (S.D.N.Y. 2008) (internal quotation marks and citation omitted). As the question of inventorship is meaningfully connected with the issue of standing, it is proper to wait until the conclusion of trial to make a determination. See All. For Envtl. Renewal, 436 F.3d at 88 (stating that "where the evidence concerning standing overlaps with evidence on the merits, the Court might prefer to proceed to trial and make its jurisdictional ruling at the close of the evidence").

iii. Substitution Is Appropriate

"Substitution of a successor in interest . . . under Rule 25(c) is generally within the sound discretion of the trial court.'" Taberna Capital Mgmt., LLC v. Jaggi, No. 08 Civ. 11355 (DLC), 2010 WL 1424002, at *2 (S.D.N.Y. Apr. 9, 2010) (quoting Organic Cow, LLC v. Center for New Eng. Dairy Compact Research, 335 F.3d 66, 71 (2d Cir. 2003). "[D]istrict courts within the Second Circuit have suggested that a primary consideration in deciding a motion pursuant to Rule 25(c) is whether substitution will expedite and simplify the action." Banyai v. Mazur, No. 00 Civ. 9806 (SHS), 2009 WL 3754198, at *3 (S.D.N.Y. Nov. 5, 2009); see also FDIC v. Tisch, 89 F.R.D. 446, 448 (E.D.N.Y. 1981) ("The decision to order substitution or joinder is to be made by considering how the conduct of the lawsuit will be most facilitated").

Substitution is appropriate here. The terms of the March 2010 Agreement provide that upon early termination of the agreement by Allergan, any assigned rights to Fein's intellectual property—the parameters of which remain to be determined—revert to Reprise and Serenity. (March 2010 Agreement § 13.5(b).) Counterclaim Plaintiffs intend to pursue these

alleged interests vigorously at the upcoming trial. All relevant discovery has already occurred and will be unaffected by the substitution. Substitution will "not affect the substantive rights of the parties," and any arguments that could have been used for or against Allergan can be used with Counterclaim Plaintiffs now in their place. Travelers Ins. Co., 164 F.R.D. at 164 (S.D.N.Y. 1995) (collecting cases). Accordingly, the motion to substitute parties is granted.

The Parties' Motions to Seal are Granted

Both parties have also moved to have portions of their respective memoranda of law and accompanying declarations sealed pursuant to the protective order previously filed in this case. (See Dkt. No. 124.) These are judicial documents "relevant to the performance of the judicial function and useful in the judicial process" and to which a "presumption of access attaches." Lugosch v. Pyramid Co. of Onondaga, 435 F.3d 110, 119 (2d Cir. 2006); see id. at 119-20 (outlining the competing interests to be weighed when sealing materials). After considering the presumption of public access to judicial documents against the privacy interests of the proprietary and confidential materials submitted, both motions are granted. See

In re New York Times Co. to Unseal Wiretap & Search Warrant Materials, 577 F.3d 401, 410 n.4 (2d Cir. 2009) ("When litigation requires disclosure of trade secrets, the court may disclose certain materials only to the attorneys involved."); Encyclopedia Brown Prods., Ltd. v. Home Box Office, Inc., 26 F. Supp. 2d 606, 612 (S.D.N.Y. 1998) ("Potential damage from release of trade secrets is a legitimate basis for sealing documents and restricting public access during trial." (collecting cases)).

Conclusion

For the reasons set forth above, Ferring's motion to dismiss is denied, Counterclaim Plaintiffs and Allergan's motion for substitution is granted, and both parties' motions to seal are granted. The Clerk of the Court is requested to amend the caption by substituting Reprise and Serenity for Allergan as counterclaimants.

In light of the protective order entered in this case, the parties are directed to jointly submit a redacted version of this Opinion to be filed publically within one week of the date of this Opinion.

It is so ordered.

New York, NY
September 7, 2017

A handwritten signature in cursive script, reading "Sweet", written in dark ink.

ROBERT W. SWEET
U.S.D.J.